RESPONSE TO OBJECTION TO ABSTRACT AND TO SUGGESTION CONCERNING THE SPECIFICATION.

The Office Action objects that the abstract of disclosure is too long. Correction has been required. A reformatted substitute specification and an amended abstract are filed under separate cover concurrently herewith. No change in the meaning of the specification or claims is intended by the reformatting and no new matter has been added. Changes made by amendment are identified.

CLAIM REJECTIONS - 35 USC § 102

Claims 33 - 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Leal (U.S. Patent 5,199,872).

Summary:

This traverse shows in detail that Applicant's check pocket anchor is patentably distinct from Leal's device, and that Applicant's claims do not read on Leal. The anchor is distinct in the following respects, each of which alone is sufficient to negate anticipation by Leal:

1. Applicant's anchor fits within a single cheek pocket of a user, where as Leal's device spans most of a user's mouth including both of a user's cheek pockets, both of the user's jaw arches, the user's tongue, and the user's lips. Leal, FIGS 1, 2, 4 and 5. In Applicant's independent claim 33 the anchor is limited as "adapted to be placed in a user's cheek pouch" (in the singular).

2. In claim 33, Applicant's anchor is limited to "compress as a user's jaws close" and to "expand ... as a user's jaws and lips open and close." This capability is contrary to Leal's stated function to maintain a patient's mouth in an open position. (Leal, col. 1, lines 6-9, lines 31-38; col. 5, lines 13-33; col. 6, lines 7-10, lines 29 -34; FIG. 2.) Leal teaches away from Applicant's device.

3. Applicant's anchor is more simple, less bulky, and less intrusive than Leal's device. Invention can lie in the elimination of elements in a prior art device, or in a reduction in the bulk, or a reduction of intrusiveness of a prior art device.

4. Leal's coils 40 do not operate in the manner stated in the Office Action; that is, the Office Action mis-perceives the manner in which Leal's device functions. Leal's coils 40 do not operate upon "the whole span size" of Leal's device, but rather only clamp separate

cotton elements to Leal's upper section 12 and lower section 14. Leal does not disclose any capacity to conversely adjust multiple loop span sizes to adjust the whole spring element span size.

5. As to Applicant's claim 35, the definition of "conduit" stated in the Office Action is inconsistent with the definition explicitly stated in Applicant's specification, para. [0224]. The definition stated in the Office Action does not conform to dictionary definitions. Leal's cotton does not function as a "conduit" as defined in Applicant's specification and in dictionary definitions and as used in claim 35.

6. The refusal in the Office Action to consider limitations following the phrase "adapted to ..." is contrary to the MPEP and to modern case law cited in the MPEP.

Applicant uses the phrase "adapted to ..." in the body of the claims, not in the preamble. Applicant uses the phrase "adapted to ..." to state positive, non-optional limitations, as is permitted by MPEP and cases cited in the MPEP.

The old appellate case cited in the Office Action narrowly ruled that use of the phrase "adapted for..." in "the introductory clause" (that is, in the preamble) of a claim did not state a patentable distinction. The appellate case cited in the Office Action arose before enactment of the Patent Act of 1952 and no longer is good law for the proposition that use of the phrase "adapted to ..." is per se objectionable, if the case ever did stand for that broad proposition (which is doubtful). More recent appellate decisions have approved use of the phrase "adapted to ...".

In Claim 33 the Cheek Pouch Anchor Is Limited to Fit Within A Single Cheek Pouch; Leal's Device Does Not Fit Within A Single Cheek Pouch.

Applicant's cheek pouch anchor is expressly limited in claim 33 to fit within a single cheek pouch:

> "A spring element adapted to be placed within a user's cheek pouch, ..." (note the singular "cheek pouch"). See Appellant's FIG. 3, resilient filament 28 and its sub-parts 28a - d, 29 and 29a.

Applicant specially defines the phrase "User's cheek pouch" in Specification, paragraph [0041]. As expressly defined a user has two cheek pouches, one on each side of the user's mouth.

Leal's device does not fit within only one cheek pouch.

Viewing Leal's FIG. 1, the leg portions 20 and 22 and the two resilient connections 24 of the Leal device are designed to fit simultaneously into both of a patient's cheek pouches. The forwardly projecting tabs 32 and 34 attached to front portions 16 and 18 of Leal's device evidently must project out between the patient's open lips, that is, must project outside of the cheek pouches. This enables the dentist to grasp tabs 32 and 34 for insertion and removal of the device. Leal FIG. 2.

The perspective in Leal's FIG. 2 can be deceptive when viewed by itself. FIG. 2 must be elucidated by reference to FIG. 1. Leal's U-shaped tongue depressor (26) evidently projects over the patient's tongue within the U-shaped space outlined by the patient's dental arches, that is, it must reside outside of the patient's cheek pouches. (col. 3, line 67 to col. 4, line 35, FIG. 1, elements labeled 26, 28 and 30.) Leal's FIGS. 4 and 5 also have the same features as Leal's FIG. 1, confirming that the Leal device simultaneously occupies both cheek pouches and also extends beyond both cheek pouches.

By patentable distinction from Leal, Applicant's cheek anchor is limited to fit within a single cheek pouch of a user.

Leal's Device is Explicitly Limited
to Prevent the Patient's Jaws From Closing.

Leal teaches away from Applicant's invention. Leal's device is explicitly designed not to compress as the patient's jaws close, but rather Leal's device is explicitly limited to prevent the patient's jaws from closing as his specification states:

> "The present invention relates to a dental appliance and particularly to a dental appliance for isolating the operative area of a patient's mouth and maintaining the patient's mouth in an open position, exposing such area." (Leal, col. 1, lines 6 - 9).

> "...., the principal features of [the present invention] provide for isolation of the operative area of the patient's mouth and prevents the patient from closing his mouth during the performance of dental work." (Leal, col. 1, lines 31 - 38.)

> "What is claimed is: 1. A dental appliance for isolating an operating area of the

mouth of a human patient and maintaining the mouth in an open position comprising: ....said resilient connection maintaining said upper and lower sections spaced in an operative orientation a predetermined distance one from the other such that, upon placement of the appliance in a patient's mouth, the appliance maintains the patient's mouth in an open position; ...." Leal Claim 1 (col. 6, lines 7 - 10 and lines 29 - 34.)

In Leal's device, the dentist manually depresses tabs 32 and 34 to compress Leal's device, then inserts the compressed device into the patient's mouth and slowly releases the compression:

"It will be appreciated that by releasing the tabs 32 and 34, the wire exerts pressure on the upper and lower jaws of the patient to maintain the mouth in an open position, while simultaneously isolating the area for dental work. Note also that the entire appliance is open along its front edge, facilitating access to the operative area by the dentist." (col. 5, lines 13 - 33 and FIG. 2.)

If Leal's device were to compress as the patient's jaws close then Leal's device would fail to perform its intended function to "maintain the [patient's] mouth in an open position" and "prevent the patient from closing his mouth."

Thus, Leal affirmatively teaches away from Applicant's claim 33 which Applicant has explicitly limited to "compress as a user's jaws ***close***" and to maintain a bridging span "as a user's jaws and lips open and ***close***."

Claim 33 and Its Depending Claims Have a Limitation That Leal Does Not Have: Applicant's Spring Element Must Be Able to Compress As A User's Jaws Close And Expand As a User's Jaws Open.

Appellant respectfully urges that following statement in the Office Action is incorrect in that it misstates the manner in which spring element (40) of the Leal device operates:

"Leal discloses a check anchor device (10) for maintaining mouth position (col. 1, lines 64-66), comprising a spring element (40) adapted to be placed in the cheek pouch, *compressed when the jaw is closed, and to resiliently expand to open the mouth during a procedure* (col. 1., lines 7-12).

Leal's coils 40 simply do not operate in that manner, as is showed in detail below.

Leal's Coils 40 Clamp Cotton Rolls; They Do Not Operate By Reason of Opening or Closing of the Patient's Jaws.

Leal's coils 40 clamp Leal's cotton rolls to the Leal device. There is no objective suggestion in Leal's patent that coils 40 are operated by the opening or closing of the patient's jaws.

Applicant invites the Examiner to particularly point out any objective teaching or suggestion in Leal's patent that Leal's coils 40 operate dynamically while the Leal device is in a patient's mouth, rather than statically clamping cotton rolls to the Leal device while the device is in the patient's mouth.

A detailed evaluation of the Leal patent follows.

The spacing between Leal's upper section 12 and lower section 14 is controlled by the spring-like action of Leal's two resilient connections 24 that operate about Leal's principal axis A-A. It is Leal's resilient connections 24, not coils 40, that urge expansion and resist compression of Leal's device 10 as a whole. (Leal, col. 3, lines 59 - 64.)

Leal's four coils 40 operate to control two smaller spaces:

(i) two coils 40 control the space between Leal's clamping element 36 and upper element 12, and

(ii) two coils 40 control the space between Leal's clamping element 38 and lower element 14. (Leal, col. 4, lines 36 - 50, col. 4, line 56 - col. 5, line 7.)

That is, Leal's resilient connections 24 tend to operate independently from Leal's coils 40. This can be inferred because the disclosed function of Leal's clamping elements 36 and 36 and coils 40 is to control Leal's cotton rolls while the Leal device is placed in the patient's mouth. This inference is corroborated by Leal's FIG. 1. After the cotton rolls have been clamped onto the Leal device and are fixed there by coils 40, then the dentist (using his fingers as in FIG. 2) operates tabs 32 and 34 to compress resilient connections 24 about axis A-A when the dentist inserts the device 10 into and removes the device 10 from the patient's mouth. (col. 5, lines 13 - 30.)

If the Examiner perceives some other mode of operation of Leal's coils 40 and elements 36 and 38, then Applicant respectfully invites the Examiner to particular point out that mode of operation.

REFUSAL TO CONSIDER THE PHRASE "Adapted to...".

The Office Action states

"The 'adapted to ... " language has not been considered since it has been held that the recitation that an element is 'adapted to' perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson,* 69 USPQ 138."

The "adapted to ..." phrase is stated in the body of Applicant's claims 33 and 38 following the words "comprising" or "comprises." The phrase "adapted to ..." is intended to, and does, state positive limits in those claims; that is, the limitations are required elements, not optional, in Applicant's claims. See MPEP 2106.C and MPEP 2111.04.

In MPEP 2173.05(g) the USPTO has adopted the modern view that the "adapted to ..." phrase can be employed to state a valid functional limitation, citing *In re Venezia, 530 F. 2d 956, 189 USPQ 149 (CCPA 1976).*

In *In re Hutchinson*, the phrase "adapted for" appeared in the "introductory clause" (that is, in the preamble before the word "comprising") of claims 42 and 43 that were at issue. *In re Hutchinson*, 33 C.C.P.A. 879 at 882-883. Thus, *In re Hutchinson* does not stand for the proposition that the phrase "adapted for" has no patentable weight where it is recited in the body of the claim after the word "comprising".

The MPEP does not cite or adopt *In re Hutchinson* for the proposition stated in the instant Office Action. The portion of *In re Hutchinson* that discusses the "adapted for..." phrase was written in 1946. The Patent Act of 1952 then was enacted. Twice thereafter the Court of Customs and Patent Appeals affirmed use of the phrase "adapted to ....". *In re Land and Rogers*, 386 F.2d 866, 872, 882, 885, 54 C.C.P.A. 806, 151 U.S.P.Q. 621 (CCPA 1966); *Venezia, supra* 530 F.2d 956 at 959 (CCPA 1976).

Applicant's search has not disclosed any published opinion of either the Court of Customs and Patent Appeals or the Federal Circuit Court of Appeals during the sixty years after *In re Hutchinson* was decided that cites *In re Hutchinson* for the proposition that the phrase "adapted to ..." cannot state a limitation in a patentable sense.

In re Hutchinson has been cited for a different proposition concerning double patenting. *In re Homer E. Allen, Deceased, 52 C.C.P.A. 1315; 343 F. 2d 482; 145 U.S.P.Q. (BNA) 147 (1965).* In 2003 a United States District Court cited *In re Hutchinson* concerning "inferential claiming" in which a new element of a claim is introduced in the middle of a

clause defining another element, but the phrase "adapted for ..." was not in issue in that case because the disputed claims did not use the phrase "adapted for ...." *Metrologic Instruments, Inc. v. PSC Inc., District of New Jersey, Civil No. 99-4876, 2003 U.S. Dist. LEXIS 26636, sections [*113] - [*114] and Appendices A - D, [*131] - [*143].*

If the Examiner can locate any published federal court appellate decision that follows *In re Hutchinson* in wholly refusing to consider the phrase "adapted to ...", then Applicant respectfully requests that the Examiner point out that citation.

Applicant respectfully submits that the *per se* refusal in the instant Office Action to consider anything that follows the "adapted to..." phrase is an error of law.

The Conduit Element of Claim 35 and the Leal Cotton Element.

The Office Action states:

> "The device (10) [of Leal] has a conduit col. 4, lines 56-63) for fluid. Examiner has given the term conduit its broadest, most reasonable definition, which is an element with a hole therethrough that can transfer air of fluid, which is the cotton surround the spring element (40)."

Applicant traverses both the Examiner's definition of "conduit" and the Examiner's characterization of Leal's cotton element as a conduit.

"Conduit" Is Defined In Applicant's Specification.

Applicant's Specification, para. [0224], explicitly states a detailed definition of "conduit" for the purposes of the claims. Applicant's basic definition is "a hollow tube or channel capable of conveying fluids along its longitudinal axis, which axis may be curved. ...."

Where a specification explicitly defines a word, the Examiner is not free to create and apply a differing definition. MPEP 2106.C.; MPEP 2173.05(a), subd. I.; *In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). See also MPEP 2111.01, subd. IV.*

The definition of conduit stated in the Office Action, an element with a hole therethrough, is unreasonably vague and indefinite. The definition in the Office Action is idiosyncratic. The Office Action does not cite any published dictionary or other authoritative source for its definition.

Applicant's explicit definition in Specification, para. [0224], is consistent with the ordinary and customary meaning stated in dictionaries that define "conduit" as follows:

"1. a channel for conveying water or other fluid. 2. a tube or trough protecting electric wiring. ORIGEN ME: from OFr., from med. L. *conductus,* from L. *conducere* (see conduct)." Oxford University Press (electronic version supplied with the WordPerfect word processing program, ver. 13, Corel Corporation, 2005).

"n. [ME. & OFr < L. *conductus.* pp. of *conducere*; see CONDUCE]. 1. a pipe or channel for conveying fluids. 2. a tube or protected trough for electric wires. 3 [Archaic], a fountain." Webster's New World Dictionary of the American Language, College Edition, 1959, The World Publishing Company, Cleveland and New York.

"1. a channel for conveying fluids. 2. a structure containing ducts for electrical conductors or cables." Random House Webster's Dictionary, 1993, Random House, Inc., New York.

"*n.* a channel or pipe conveying water or other fluid or covering electric wires, etc.: a fountain for supplying the public with water. [Fr. *conduit* - L. *conductus* - *conducere,* to lead.] Chambers's Twentieth Century Dictionary, 1965, Hawthorne Books, Inc., New York.

The definition stated in the Office Action is not consistent with these dictionary definitions.

Claim 35 and the Leal Cotton Element.

The Office Action exploits indefiniteness in the Office Action's idiosyncratic definition of "conduit" to unreasonably and incorrectly characterize the cotton element in Leal (U.S. Patent 5,199,872) as a "conduit."

Leal states in relevant part:

> "In the preferred form of the present invention, as illustrated in FIGS. 2 and 3, conventional cotton rolls may be applied to the appliance 10 for the purposes of cushioning the appliance with respect to the soft tissues of the patient's mouth and to provide for absorption of saliva." (col. 4, lines 50 - 55.)

> "By locating the cotton rolls along the front and leg portions of each of the upper and lower sections, as described, the soft tissues of the mouth are fully protected from

the wire of the appliance, while simultaneously the cotton rolls absorb the saliva." (col. 5, lines 1 - 10.)

Thus, Leal teaches use of his cotton element for cushioning and absorption. Dictionary definitions of "absorb" are as follows:

"1. soak up (liquid or other substance)." Oxford University Press, electronic version provided with WordPerfect, version 13, Corel Corporation, 2006.

"1. to take up or drink in (a liquid); soak up." Random House's New World Dictionary, Random House, Inc., New York, 1993.

Leal does not disclose or teach use of the cotton element as a conduit, in the sense of a channel or tube to convey fluid. The assertion in the Office Action that Leal's cotton element would act as a conduit is speculation that lacks any objective foundation in the Leal patent.

Leal's description of his cotton element as an absorbent is incompatible with the fluid-conveying function of a conduit. An absorbent soaks up and holds fluid, rather than conducting fluid from one place to another.

Workpieces Can Be Joined To and Positioned By Applicant's Cheek Pouch Anchor, But Such Workpieces Themselves Are Not Claimed As Elements Of the Cheek Pouch Anchor In Claims 33, 34, and 36-38.

Applicant's claim 33 does not claim the "work piece" as an element of the invention, but rather claims as positive limitations the capability "to receive joinder to a work piece" and "having structural strength sufficient, when joined to a work piece, to maintain placement within a user's cheek pouch while a user's lips and jaws open and close."

The Examiner correctly perceives that cotton used as taught in Leal or Diaz could be carried and positioned by the cheek pouch anchor of claims 33, 34 and 36. However, that cotton then would be a "work piece", not an element of the invention claimed in Applicant's claims 33, 34 and 36.

Similarly, Applicant's claims 37 and 38 do not claim the "substance to be released in a user's mouth" as an attribute of the "spring element", but rather the "substance to be released" is a non-claimed workpiece. The attribute of the "spring element" that is

positively claimed in claims 37 and 38 is the capability "to receive impregnation or coating" with the "substance to be released."

The Examiner has correctly noted that premoistened cotton, similar to the disclosure of *Diaz, U.S. Patent 4,041,937 (col. 1, lines 58-61)*, was well known in the prior art as a method to release a substance in the mouth. The Examiner also correctly perceives that such a well known use of cotton would be one way to adapt the spring element of Applicant's claims 37 and 38 "to receive impregnation or coating with a substance that is to be released." When so used as an adaptation to enable impregnation or coating of the spring element, then the cotton would fall within the invention claimed in claims 37 and 38. See Applicant's specification, p. 2, para. [0032].

By distinction, in dependent claim 35 the "conduit" is positively claimed as an additional element of the invention in addition to the spring element of claim 33. That is, within the meaning of the phrase "work piece" in claim 33, the conduit is a particular type of work piece that is claimed in claim 35 as an additional element of the invention in claim 35.

In Claim 36 A Plurality of Conversely-adjustable Loops Enables User Adjustment of the Whole Spring Element Span Size.

The Office Action states:

"The device (10) (of Leal) is formed of metal (col. 1, lines 52-55) and configured into a plurality of loops (fig. 1), wherein *if one loop has its span increased or decreased it will result in another loop increasing or decreasing space* because the device is made of continuous pieces of wire. *The plurality of loops is combined to form a spring element (40)* with an element span size (fig. 1)."

Applicant traverses the quoted statement, and in particular traverses the two italicized statements. Applicant respectfully urges that the Office Action misstates the manner in which Leal's spring elements (coils 40) function.

LEAL LACKS A PLURALITY OF LOOPS THAT COMBINE TO FORM A WHOLE SPRING ELEMENT WHERE SUCH LOOPS HAVE SPAN SIZES THAT ARE MUTUALLY ADJUSTABLE RELATIVE TO EACH OTHER TO ADJUST THE WHOLE SPRING ELEMENT.

Leal's coils 40 and clamping elements 36 and 38 are not a "plurality of loops [that]

are combined to form a whole spring element" which is adjustable, as that limitation is stated Applicant's claim 36.

Leal's coils 40 and clamping elements 36 and 38 evidently operate independently from Leal's "resilient connection" 24. The following mechanical analysis of Leal's written disclosure and drawings shows why this is so.

Leal states that his axis A-A in FIG. 1 is the axis of displacement along which "upper and lower sections 12 and 14 may be resiliently displaced toward and away from one another." (Leal, col. 3, lines 59 - 66 and col. 4., lines 3 - 8.)

The resilience which achieves a spring-like effect in Leal's device inheres in the "resilient connection" (24) of Leal's upper and lower sections 12 and 14. Leal describes it as follows:

> "The leg portions of said [generally U-shaped] sections are connected to one another adjacent rear end portions thereof and transverse opposite sides of the appliance, the connected rear end leg portions form a resilient connection between the upper and lower sections, enabling movement of the upper and lower sections toward and away from one another about an axis extending generally transversely of the appliance. The resilient connection maintains the upper and lower sections spaced in an operative orientation a predetermined distance one from the other such that, upon placement of the appliance in a patient's mouth, the appliance maintains the patient's mouth in an open position." (Leal, col. 2, line 68 to col. 3, line 13.)

There apparently are two resilient connections 24 at either end of axis A-A in Leal's FIG. 1, though only one is labeled 24 and Leal sometimes speaks of "connection 24" in the singular.

Leal's specification and drawings do not state or show that coils 40 and clamping elements 36 and 38 operate as spring elements ***about axis A-A*** to compress or expand the space between Leal's upper and lower sections 12 and 14.

Leal does not suggest, and Applicant does not perceive, any mechanical way in which Leal's coils 40 on clamping elements 36 and 38 could function as spring elements controlling the resilient displacement of Leal's upper and lower sections 12 and 14 relative to each other about axis of displacement A-A. If the Examiner perceives how coils 40 and clamping elements 36 and 38 can operate upon Leal's axis A-A, then Applicant respectfully invites the Examiner to point out how this is disclosed in Leal.

Leal teaches that displacement about Leal's axis A-A is controlled by Leal's "resilient connection" 24 (col. 3, lines 59 - 66), not by coils 40 on clamping elements 36 and 38. (col 4, line 64 - col. 5, line 7.)

Leal describes the operation of his coils 40 and "clamping elements 36 and 38" as follows:

> "In one form of the present invention, a pair of elements, generally semi-elliptical in shape, are pivotally secured to the rear-end portions of the upper and lower sections and extend between and are spaced from the sections to form upper and lower clamps. These clamps releasably secure a flexible cushioning and absorbent material along the upper and lower sections. More particularly, cotton rolls may be applied to one or the other of the upper section or associated clamping element by slitting the rolls lengthwise and inserting the section or element lengthwise along the slit. The element thus clamps a portion of the cotton roll between the element and the upper section to maintain the roll in position, not only to cushion the appliance within the patient's mouth but also to absorb saliva. The cotton rolls may similarly be applied along the lower section and its associated clamping element, along the leg portions of the upper and lower sections, and along the tongue depressor. The cotton rolls are movable with the upper and lower sections during insertion and withdrawal of the appliance." (Leal, col. 2, lines 19 - 40.)
>
> "In this preferred form of the invention illustrated in FIGS. 1 - 3, there is additionally secured to the upper and lower sections 16 and 18 clamping elements 36 and 38, respectively. Clamping elements 36 and 38 each comprise wires which are shaped generally in conformance with the upper and lower sections 12 and 14 and which have one or more coils 40 adjacent to their rear end portions whereby the elements 36 and 38 may be pivoted from their orientation spaced from the upper and lower sections to a position enlarging the space between the element and its corresponding section. Coil springs 40 thus bias elements 36 and 38 into the illustrated positions spaced from the corresponding sections. The ends of elements 36 and 38 are secured to the wires forming the rear portions of the upper and lower sections." (Leal, col. 4, lines 36 - 50).

As disclosed, Leal's coils 40 and clamping elements 36 and 38 do not act as a spring

elements that control expansion and compression of Leal's device 10 *as a whole* about axis A-A. Rather, Leal's coils 40 and clamping elements 36 and 38 act as spring elements to clamp cotton rolls to the upper and lower sections 14 and 16.

Leal's drawings do not specifically label the point(s) or axis(es) about which Leal's clamping elements 36 and 38 "may be pivoted". However, Leal's specification states that "a pair of elements, generally semi-elliptical in shape, are pivotally secured to the rear-end portions of the upper and lower sections and extend between and are spaced from the sections to form upper and lower clamps." (col. 2, lines 19 - 23.)

In Leal's FIG. 1, clamping element 36 is not depicted as being in contact with upper section 12 in the vicinity of finger tab 32. Consistently with this perception of FIG. 1, Leal's specification indicates only that clamping element 36 is "pivotally secured to the rear-end portion" of upper section 12. (Leal, col. 2, lines 19 - 24.)

In Leal's FIG. 1, clamping element 36 is depicted in contact with upper section 12 at the two ends of the wire from which clamping element 36 is formed, closely adjacent to coils 40. These two contact points between clamping element 36 and upper section 12 are some distance forward of axis A-A and resilient connections 24 -- and thus coils 40 cannot pivot about axis A-A.

The pivot function of Leal's clamping element 36 and its two coils 40 cannot mechanically operate directly upon axis of displacement A-A. Rather, clamping element 36 and its coils 40 can act directly only upon upper section 12. Leal's patent does not objectively teach or suggest that the pivot action of clamping element 36 and coils 40 interacts cooperatively with resilient connections 24 and axis A-A.

This same functional analysis also applies to clamping element 38 and its two coils 40 which can act directly upon lower element 14, but do not to operate directly upon axis of displacement A-A and resilient connections 24.

In accord with the foregoing analysis, one can infer that when Leal's finger tabs 32 and 34 are compressed towards each other to reduce the span of Leal's whole device 10, the compression state of Leal's coils 40 and clamping elements 36 and 38 generally will tend to remain unaffected. That is, one can infer that coils 40 will tend to operate relatively independently from resilient connections 24. One can infer that coils 40 operate relatively independently from resilient connections 24 in order to allow coils 40 to stabilize the cotton rolls held by clamping elements 36 and 38 while the Leal device is being inserted into, is

resident in, and is being removed from the patient's mouth.

In any event, there is no express teaching or suggestion in Leal that objectively supports the assertion in the Office Action that Leal discloses "a spring element (40) adapted to be placed in the cheek pouch, compressed when the jaw is closed, and to resiliently expand to open the mouth during a procedure." The Office Action incorrectly cites Leal, col. 1, lines 7 - 12, for this assertion but the passage of Leal cited in the Office Action does not attribute that function to Leal's coils 40.

Although one might speculate that it might be possible to crush Leal's clamping elements 36 and 38 and coils 40 against each other by extreme manual compression of Leal's tabs 32 and 34 (assuming that resilient connection 24 could tolerate such extreme compression), still that extreme range of motion is not taught or suggested in Leal's patent. There is no suggestion in Leal that a patient could achieve such extreme compression by closing the patient's jaws. To the contrary, Leal's device is expressly limited to prevent closing of the patient's jaws.

LEAL'S DEVICE LACKS A CAPACITY FOR ADJUSTMENT OF THE WHOLE SPRING ELEMENT SPAN SIZE BY MUTUALLY CONVERSE INCREASE OR DECREASE OF THE RELATIVE SPAN SIZES OF A PLURALITY OF LOOPS THAT FORM THE WHOLE SPRING ELEMENT.

Applicant's device has an additional capability that Leal's device lacks. As stated in Applicant's claim 36, the "whole spring element span size" of Applicant's device can be adjusted, by "***converse*** increase or decrease" of the relative sizes of a plurality of loops relative to each other.

Applicant's Specification, description of Fig. 1, para. [0192], discloses this capability as follows:

> "Loops 28a, 28b, 28c, and 28d combine to form the whole loop span formed by the flexible, resilient filament 28. By tugging on curled loop ends 29 and 29a a user can lengthen loops 28b and 28d and shorten loops 28a and 28c; conversely, by tugging on loops 28a and 28c a user can lengthen those loops while shortening loops 28b and 28d, thus enabling a user to adjust the whole loop span of filament 28 for better fit."

Leal does not disclose any capacity for a user to adjust the operating range of Leal's

resilient connections 24 that operate about axis of displacement A-A. That is, Leal does not disclose any capacity for user adjustment of the maximum size of the span between Leal's upper section 12 and lower section 14.

Leal describes the formation of his device as follows:

> "In the preferred form, appliance 10 is formed of a metallic wire. For ease of constructing the appliance 10, the wire forming the upper and lower sections 12 and 14 and the connective portions 24 may initially be formed into a flat elliptical shape. The opposite ends of the elliptically-shaped wire may then be folded or bent ***about the minor axis of the ellipse, i.e., about axis A-A,*** to space the two semi-elliptical portions forming the upper and lower sections 12 and 14, respectively, in the manner illustrated in FIG. 1." (Leal, col. 3, line 67 to col. 4, line 8.) (emphasis added).

By geometric definition, the major and minor axes of an ellipse pass through the center of the ellipse and the foci of the ellipse fall on the major axis. *Calculus with Analytic Geometry, 2nd Ed., Johnson, R.E. and Kiokemeister, F. L., Allyn & Bacon, Inc. Boston, 1960, § 5, pp. 173 - 175.* Thus, by definition, the minor axis is at a fixed place on an ellipse. Therefore, as disclosed by Leal, Leal's axis of displacement A-A is set at a fixed place, to wit, on the minor axis of Leal's ellipse.

From Leal's disclosure, it appears that Leal's upper section 12 and lower section 14 have fixed, equal loop span sizes because they are formed about the minor axis of Leal's ellipse. (Leal, col. 3, line 67 - col. 4, line 9, and FIGS. 1, 4 and 5.) It reasonably can be inferred that the sizes of Leal's upper section 12 and lower section 14 are not intended to be adjusted relative to each other by the user. In any event, Leal does not teach how to achieve any such adjustability.

Using the teaching of Applicant's invention by hindsight, Applicant perceives that one could displace the location of axis A-A on Leal's ellipse away from the minor axis of Leal's ellipse and thereby increase one loop of Leal's ellipse and conversely decrease the other loop of that ellipse. For example, the loop size of Leal's upper section 12 could be increased by decreasing the loop size of lower section 14.

However, Leal's patent does not objectively suggest that a user can adjust Leal's device by re-folding or re-bending Leal's elliptically shaped wire at some location other than the minor axis of the ellipse in order to shift the location of axis A-A on the ellipse and

thereby alter the span of Leal's upper section 12 and lower section 14 relative to each other.

Leal does not teach or suggest any mechanism for "converse" adjustment of the relative sizes of a combined plurality of loops to adjust the span size of the whole spring element.

The Office Action does not identify, and Applicant does not perceive, in Leal's disclosure any motivation to displace Leal's axis A-A away from the minor axis of Leal's ellipse, but Applicant does perceive an obvious disadvantage of any such displacement in Leal's device. Displacement of Leal's axis A-A away from the minor axis of Leal's ellipse would render Leal's upper and lower sections 12 and 14 asymmetric to each other. Such asymmetry would offset sections 12 and 14 relative to each other and would tend to offset Leal's tabs 32 and 34 relative to each other. This offset would tend to make it more difficult for the dentist to compress tabs 32 and 34 with his fingers (as in FIG. 2)and thus would tend to compromise the cooperative function of the Leal's tabs 32 and 34.

If the Examiner, without the benefit of hindsight, perceives any teaching, suggestion, or motivation in the Leal patent for converse, relative adjustment of Leal's upper and lower sections 12 and 14 to enable user adjustment of the whole spring element span size of Leal's device 10, then Applicant respectfully invites the Examiner to particularly point that out in the Leal patent.

CLAIM REJECTIONS - 35 USC § 103.

The Office Action rejects claims 37 - 38 under 35 U.S.C. § 103(a) as being unpatentable over Leal (U.S. Patent 5,199,872) in view of Diaz (U.S. Patent 4,041,937).

Applicant traverses this rejection as a whole.

Summary:

1. The proposed combination of Leal with Diaz does not yield the elements of Applicant's invention in claims 37-38. This is because Leal does not substantially disclose Applicant's cheek pocket anchor, as explained above in Applicant's traverse of the assertion that Leal anticipates Applicant's cheek pocket anchor in claims 33-36.

2. Applicant discusses the impact of the new decision that was rendered in April 2007 in *KSR International Co. v. Teleflex, Inc., 2007 U.S. Lexis 4745,* concerning the

proper way to analyze obviousness. Applicant shows that the Office Action fails to state a prima facie case that Applicant's claims 37 and 38 are obvious.

3. The prior art cited in the Office Action teaches away from Applicant's cheek pocket anchor. The prior art cited in the Office Action teaches how to use spring elements to hold a patient's jaws open, or to retract mouth tissues to hold them apart, whereas Applicant's anchor is specifically disclosed and claimed to operate while the patient's jaws and lips are free to open and close.

4. Applicant's specification at paras. [0058]-[0064] identifies and quantifies a problem in prior art for stabilization of cheek path airway devices. That problem is solved by Applicant's cheek pouch anchor.

5. Applicant's anchor, designed to solve the airway stability problem, turned out to also have the unanticipated capacity to be adapted to carry substances for release within a patient's cheek pocket, without limiting the opening and closing of a patient's jaws and lips and without interfering with a patient's tongue and swallowing.

THE OFFICE ACTION DOES NOT ARTICULATE PRIMA FACIE OBVIOUSNESS.

The U.S. Supreme Court's recent decision requires that an analysis of obviousness must be explicit; rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR International Co. v. Teleflex, Inc., Supreme Court of the United States, No. 04-1350, April 30, 2007, 2007 U.S. Lexis 4745* at [*40] - [*41], citing *In re Kahn, 441 F. 3d 977, 988 (CA Fed. 2006).*

The U.S. Supreme Court's recent decision ruled that it still is appropriate to search the prior art for a teaching, suggestion, or motivation to combine previously known elements in order to show that a combination is obvious. However, that inquiry for teaching, suggestion or motivation, must be part of a flexible analysis of obviousness and cannot be treated as a rigid limit on the analysis. *KSR International Co. v. Teleflex, Inc.*, supra, 2007 U.S. Lexis 4745 at [*37]-[*38], [*42] - [*43]. An examiner still must remain aware of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. *KSR International Co. v. Teleflex, Inc.*, supra, 2007 U.S. Lexis 4745 at [*42].

The Obviousness Analysis In the Office Action Is Founded Upon An Incorrect Statement of The Manner in Which the Leal Device Functions.

Applicant particularly traverses the following statement in the Office Action:

"Leal substantially discloses the claimed invention, see claim 33 rejection above, Leal fails to disclose the spring element is adapted to receive impregnation or coating with a substance to be released in the user's mouth. However, Diaz teaches cotton swab (28a) moistened with antiseptic (col. 1, lines 58-61). Therefore it would be obvious to one of ordinary skill in the art at the tie (time?) of the invention to coat the cotton of the Leal device with antiseptic to prevent infection in the mouth and provide a pleasant taste to the user."

As showed above, Leal's device is explicitly limited to prevent closure of the patient's mouth.

Leal affirmatively teaches away from the express limitation of Applicant's claim 33 that Applicant's spring element must compress as a user's jaws close.

A showing that prior art teaches away from a claimed invention makes it more likely that the claimed invention is non-obvious. *KSR International Co. v. Teleflex, Inc., supra, 2007 U.S. Lexis 4745, [*33] - [*34],* citing *United States v. Adams 383 U.S. 39 at 51-52, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293.*

Other art cited in the Office Action also teaches away from the dynamic operation of Applicant's device. That cited prior art teaches how to maintain the mouth or mouth tissues in relatively fixed, open or spread positions as follows:

Hartig, U.S. Patent 2,614,325,(col. 2, lines 43-53) teaches as follows:

"In Fig. 4, I have shown my novel invention in use in positioning cotton rolls X, one adjacent the teeth A in the upper jaw Y and one adjacent the teeth A in the lower jaw Z. It will be noted that, in such use, the looped portion 3 is positioned toward the back of the mouth, whereby the resilience of the diverging arms 2 *will tend to retain the patient's jaws apart* during the oral operation."

Levisman, U.S. Patent 6,702,739, in his abstract teaches away from Applicant's invention:

"A holder *for holding parts of a body, structure or assembly spaced apart* during

operations carried out on the body."

See also Levisman, Summary of the Invention (col. 2, lin2 64 - col. 3, line 35, claims 1 and 21, and Fig. 3. Levisman teaches how to make a retractor that fixes the positions of body parts relative to each other, whereas Applicant does the opposite: Applicant's device stabilizes itself and a work piece within the body while allowing relatively free movement of the body parts.

Rodriquez, U.S. Patent 5927,276, also teaches away as follows:

"An upper jaw frame portion extends along the inverted U-shaped portion between positions 166, 116 and 168. A mouth portion of the device 100 is formed by the upper jaw portion and the lower jaw portion *such that a patient's jaws are held open* while the mouth portion is positioned inside the mouth as shown in FIG. 4." (col. 4 lines 31 - 36.)

"Curvature of the various frame portions of device 100 as described above and as shown IN FIGS. 1-3, is preferable *in order to (1) hold a patient's jaws open*, (2) follow the contours of a patient's face without contacting the face apart from minimal contact with the lips, mouth or jaws and (3) provide attachment points for attaching a fastener for a secure and stable attachment of the device to a patient's head." (col. 4, lines 60-67.)

By way of additional distinction, the cheek-adjacent portions of Rodriguez's device lie outside the patient's mouth, not within the cheek pouch. They serve as attachment points for Rodriguez's external straps 610, 620, 720, and 730. FIGS. 12 - 13.

Thus, the Examiner's combination of Leal with Diaz does not render Applicant's claims 37 and 38 obvious. To the contrary, the "teaching away" by Hartig in 1951, by Leal in 1993, by Rodriguez in 1999, and by Levisman in 2004, all corroborate the non-obviousness of Applicant's anchor that is designed to stabilize itself within a single cheek pocket while the user's jaws remain free to open and close. *KSR International Co. v. Teleflex, Inc., supra, [*33] - [*34]; United States v. Adams, supra.*

Applicant's device could release a substance in the user's mouth "as a user's jaws open and close", but the Leal device would do so only while the patient's mouth and lips are

forcibly held open and prevented from closing by the Leal device.

Leal's device also cannot meet the limitation of Applicant's claim 33 that the spring element is "adapted to be placed within a user's cheek pouch" (in the singular). Leal's device spans most of a user's mouth. It is designed to simultaneously occupy both of a user's cheek pouches while Leal's tabs 32 and 34 evidently project between a user's open lips, and Leal's tongue depressor projects over the user's tongue. This is an independent, second reason why the Examiner's combination of Leal with Diaz cannot render Applicant's claims 37 and 38 obvious.

Applicant's Specification Identifies, Quantifies, and Solves A Problem With Prior Art.

Please note the topic "Slippage and Rotation Problems of Cheek-Side Airways" in Applicant's specification, paras [0058] - [0064]. None of the cited prior art quantifies and solves this problem as Applicant's device does.

The Risk Of Improper Hindsight Bias Is Heightened By The Simplicity of Applicant's Cheek Pouch Anchor Which Eliminates Clumsy, Bulky Stabilizing Devices Used in Prior Art.

Applicant's anchor, which fits within a single cheek pouch, is notably less bulky, more simple, and less intrusive than is Leal's device that spans most of a user's mouth including both cheek pouches, both dental arches, the tongue and the lips. See Leal, FIGS. 1, 2, 4, 5.

Invention can lie in improving the simplicity of a device or in reducing its bulk, or in reducing its intrusiveness. Applicant's anchor greatly reduces the interference by prior art devices with the normal function of a user's jaws, teeth, lips, and tongue.

SUMMARY

Applicant respectfully submits that the rejections of claims 33 - 38 should be withdrawn and those claims should be allowed. New claims 39 and 40 also should be allowed.

May 18, 2007 Lowell R. Wedemeyer

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